EXHIBIT C

IN THE UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
(CHARLESTON DIVISION)

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE NO. 2:12-MD-02327
	:	MDL NO. 2327
THIS DOCUMENT RELATES TO ALL WAVE 8 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS	:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Deposition of MARK ELLERKMANN, M.D.
Towson, Maryland
Friday, October 12, 2018
1:05 p.m.

Reported by: Linda M. Bahur, RPR

Deposition of MARK ELLERKMANN, M.D., held at:
SHERATON BALTIMORE NORTH HOTEL
903 Dulaney Valley Road
Towson, MD 21204
Pursuant to agreement, before Linda M. Bahur, a Notary in and for the State of Maryland.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:

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I N D E X
E X A M I N A T I O N

PLAINTIFF EXHIBITS

(Attached to the transcript)

DEFENSE EXHIBITS

(Exhibit No. 1 retained by Mr. Snell)

P R O C E E D I N G S

(Plaintiff Exhibit Nos. 1-4 were marked for identification.)

Whereupon --

MARK ELLERKMANN, M.D.

being first duly sworn, as hereinafter certified, testifies as follows:

EXAMINATION BY MR. FAES:

Q Good afternoon, Dr. Ellerkmann. My name is Andrew Faes and I represent various plaintiffs in this litigation, and I'm here today to take your deposition regarding the Prolift case. Do you understand that?

A Yes, I do.

Q And you understand that you're under oath and you're sworn to tell the truth; right?

A Yes.

Q And if for any reason during the course of the day I ask you a question that doesn't make sense to you, just let me know and I'll try to rephrase the question. All right?

A I will.

Q First of all, I've premarked some

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probably around 2010. Somewhere in that range.
Q And when was the last time that you implanted a Prolift device?
A Sometime around the same period of time.
Q And the Prolift+M?
A I can't give you an exact date.
Q You kind of lumped the Gynemesh PS Prolift and Prolift+M all together and state that you've utilized them in hundreds of patients. Do you have any kind of breakdown of how many Gynemesh PS devices you've implanted in a patient or patients?
A I would say Gynecare -- that Gynemesh PS, I would say I was using that prior, obviously, to launch a Prolift for prolapse repair. I would say the breakdown would be probably around 30 percent Gynecare Gynemesh PS and 70 percent -- just under 70 percent for Prolift.
Q And for Prolift+M, it's less than 5 percent or less than 2 percent?
A That is correct. Right.
Q Is it accurate to say that you probably implanted the ProliftM on less than five

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occasions?
A No, I wouldn't say that's accurate. Not less than five occasions, but less than 5 percent of the time.
Q Okay. Have you ever tracked a complication rate for the Prolift based on your personal use in your office?
A So I keep a database of my surgery, every surgery I've done even as a fellow. Not as a resident but as a fellow. I did my training here. And of that database, I kept a complication rate and still do.
Q And I don't see anywhere in your expert report where you say that you intend to state an opinion as to what your complication rate is with the Prolift®. Is that an opinion that you intend to offer in this case?
MR. SNELL: I'm going to object to the characterization. Go ahead.
A I can offer an opinion regarding my complication rate with respect to Prolift and that was that it was extremely low.
Q So extremely low. Can you put a numerator on that or a denominator or a

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percentage?
A I can put a general percentage on that. It was probably less than 5 percent.
Q And that's all complications, not just erosion?
A It depends on what complication if we look at the no classification. You know, if we're talking about Class 1 complications, maybe higher. Urinary tract infections, something like that. But if we're talking about specifically mesh exposure, mesh erosion, less than 5 percent.
Q But as you sit here today, you can't give me, say, a denominator of the total number of cases of Prolift or the numerator of the total number of cases of Prolift?
MR. SNELL: Object to form. Go ahead.
Q Complications?
MR. SNELL: Object. Form.
A No. My overall complication rate with respect to Prolift, less than 5 percent.
Q And would you agree with me that that, since you can't give me the numerator or the denominator as you sit here today, that that 5 percent isn't based on any formal analysis that

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you've done of your complication rate?
MR. SNELL: Object. You're misstating.
A No, I would not agree with that, actually, because I did look at my complication rate and it is generally less than 5 percent.
MR. FAES: Okay. Well, Counsel, if that's an opinion he's going to express at trial, we're going to request production of the data from this database that substantiates his opinion that his complication rate is 5 percent.
MR. SNELL: We'll take that up. That's for me. We'll take that up.
Q Same question with regard to the Gynemesh PS. Have you done any kind of tracking of a complication rate of your use of Gynemesh PS?
MR. SNELL: Hold on. Hold on. I'm going to object to the form and foundation of the question to the extent it assumes Gynemesh PS to be different than Prolift. You can go ahead and answer.
A So Counsel, I've told you that I kept a record of every surgery that I've done since I was a fellow. That included the use of Gynemesh PS Prolift.

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the materials listed in Exhibit 3?
A Better part of four weeks.
Q So how many hours would you say you spent on that?
A Close to 120 hours. That includes looking at these articles, refreshing my memory, and composing the manuscript, the expert report.
Q So the 120 hours includes both the review of the materials and the writing of the report; right?
A That's correct. Yes.
Q How many hours would you say you spent actually drafting your report as opposed to reviewing materials?
A Well, I took notes as I reviewed the materials and I composed my report. I had two computers going at the time, two screens. So a lot was done simultaneously, so it's hard to break it down.
Q Okay. In your reliance list, you've got --
MR. FAES: Counsel, is this his current reliance list or is there a supplemental one that I might be missing out on?

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MR. SNELL: No, I think this is his list. I don't think that he has a pending supplemental one.
MR. FAES: Everybody else supplemented theirs, so I wasn't sure. I got brought in late on this so I just wanted to make sure that there wasn't a supplemental one that I wasn't aware of.
MR. SNELL: Not that I know of.
THE WITNESS: This looks current to me.
MR. SNELL: Okay.
BY MR. FAES:
Q Who created Exhibit No. 3?
A Mr. Snell's firm.
Q Okay. So did Mr. Snell's firm provide you with all of the documents and materials listed in Exhibit No. 3?
A Did they provide me with them all?
Q Yes.
A They comprised this report. Yes. And there's other things are included in this that I shared with them that I was using in my report.
Q Okay. So it's accurate to say that they provided a large majority and then you

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supplemented it with some materials that you had reviewed and relied on on your own; is that correct?
A That is correct.
Q Did you feel like that you had everything you needed in order to form your opinions in this case?
A Well, my opinions are formulated in part due to literature and also my own clinical experience. So in terms of written literature that I reviewed, this served as the bulk of that. Yes.
Q Did you do any of your own independent literature searching for peer-reviewed literature on Prolift®?
A I did, and that's what I'm saying. It's the articles that weren't included in this are referenced and submitted ultimately in what we have before us here.
Q And I see that on your reliance list that you did review the testimony of a couple Ethicon employees? A Piet Hinoul and a Marty Wiseberg?
A I'm not sure I reviewed those in

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particular. No.
Q Okay.
A I may have glanced at them. Some of these articles that are listed here are articles I am familiar with because either my fellows wrote them or co-workers or colleagues. So that doesn't mean I read them back to back. I'm familiar. I spent my last 20, 25 years reading the literature, so that's how I spend a lot of my evenings.
Q So if I understood you correctly, you're not sure if you reviewed Piet Hinoul or Marty Wiseberg's deposition testimony?
A Yes. I'm not sure I've reviewed those in particular now.
Q Are there other materials that are listed in your reliance list that you haven't reviewed?
A I would say that most of these I have reviewed. Either read in their entirety or reviewed.
Q Most but not all?
A Right. So some of the depositions you said O'Toole. What page is that on?
Q It's the second-to-last.

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Unfortunately, you guys never put page numbers on this, which I think they do on purpose.
A Yes. So Counsel, some of the depositions and some of the email communications I would have probably not reviewed. I was looking more at Level 1, Level 2 literature as I did my report.
Q So as we sit here today, is there any kind of list out there that reflects what you actually did review and rely on in coming to your opinions in this case?
A I would say the list before us is fairly comprehensive on what I reviewed.
Q But as you stated earlier, there are some items in here that you haven't actually reviewed?
MR. SNELL: Objection as to scope of that. Go ahead.
A I would say yes to that.
Q Okay. So is it fair to say that in forming your own opinions in this case, that you haven't reviewed the deposition testimony of any Ethicon witnesses?
A Any Ethicon witnesses?

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Q Any Ethicon witnesses that worked for the company.
A Well, at least those two that you've listed here. No, I have not reviewed those. I think that's fair to say.
Q Okay. Doctor, have you ever been a party to a lawsuit?
A Yes.
Q How many times?
A Twice I'm aware of.
Q And what was your role in those cases?
A I was a defendant.
Q In both cases?
A Both cases, yes.
Q And were they both medical malpractice cases?
A Yes.
Q And when did those two cases occur?
A Yeah. One case was sometime in -- the first case, I was a fellow, and that would have been 2000, 2001. And then again about five years later -- I don't know when they were finally resolved, the exact years, but one case I was dismissed without prejudice and the other was

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settled for a nominal amount of money to cover court costs or something like that it was.
Q Were you deposed in either of those cases?
A I was deposed, I know, in the first one. Probably both of them, actually.
Q And where were you employed at the time that those occurred?
A Greater Baltimore Medical Center.
Q And do you recall the name of any of the law firms involved in those cases?
A No.
Q Do you recall the name of any of the plaintiffs in those cases?
A One plaintiff was Loftus.
Q And can you spell that for the reporter, to the best of your memory.
A Yes, L-O-F-T-U-S. And the other plaintiff I can't remember offhand.
Q And you're currently licensed in the state of Maryland; right?
A Yes.
Q And is that the only state where you're currently licensed?

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A Yes.
Q And in the past, you've been licensed in the state of Maine?
A Correct.
Q But that license is no longer active?
A That's correct.
Q When did you let that license lapse?
A When I moved to Maryland in 1998.
Q Okay. Have you ever had any -- are those the only two states where you've ever been licensed?
A Yes.
Q Have you ever had any action whatsoever taken against your medical license?
A No.
Q Never had any disciplinary action taken?
A No.
Q Never had any orders of compliance issued?
MR. SNELL: Objection. Asked and answered already.
A No.
Q Okay. Now, I notice that you've

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think I've stated that a few times now.
Q Sorry. Are you done? I didn't mean to interrupt you.
A No.
Q Have you ever drafted the IFU for a medical device?
A No, I have not.
Q Have you ever worked on warnings for a medical device?
A No, I have not.
Q Have you ever worked on warnings for a prescription drug?
A No, I haven't, but may I go back to your answer just previously? Because something came to my mind.
Q Sure.
A I am actually on a board of advisors for a development that's currently R&D. We've just actually received an N.I.H. grant for a new type of pessary -- pessary, P-A-S-S-A-R-Y [sic] -- working with colleagues at Dartmouth-Hitchcock in Hanover, New Hampshire.
So to that end, I have counseled and provided Counsel regarding warnings for pessary

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use.
Q Would you agree with me that you've never worked on the warnings for a polypropylene mesh device?
MR. SNELL: Object to form.
A Other than providing feedback at various summits and advisory meetings during my time as a preceptor with Gynecare or AMS for that matter.
Q So you actually provided feedback at seminars for Ethicon and Johnson & Johnson regarding warnings that were in the IFU for their polypropylene mesh devices?
A I would state it more different. I would state is differently, Counsel. I would say at various workshops and industry-sponsored summits, be they in Minnesota or in New Jersey, round table discussions that we had, we shared information with one another about our clinical experience, and I suspect that that information was tabulated and looked at and ultimately played a role in formulation of IFUs.
Q So during your time consulting for Ethicon specifically, did anyone at Ethicon ever

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ask you what warnings they thought should be in the IFU for one of their polypropylene medical devices, whether orally or written?
MR. SNELL: Objection. Can you read that question back?
(The last question was read into the record.)
MR. SNELL: Are you asking did someone at Ethicon ask him what warnings that Ethicon, they thought?
MR. FAES: So let me see --
MR. SNELL: I don't know if you meant that.
MR. FAES: Let me see I can reask it.
MR. SNELL: I think I know what you're trying to ask but the question was really --
BY MR. FAES:
Q During your time consulting for Ethicon and Johnson & Johnson, did anyone at Ethicon ever ask you your opinion regarding what warnings you thought should be in a polypropylene mesh device?
A Not that I'm aware of specifically.
Q Would you agree with me that you never worked on warnings for a Class 3 medical device?

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A I would agree. I mean, I think we all know that these devices were elevated to a Class 3 device at one point. But at that point in time, no, I never worked directly with that.
Q Would you agree with me that physicians should be made aware of all the significant safety risks associated with the Prolift in the IFU?
MR. SNELL: Objection. Asked and answered.
A Yes. I've answered that. I would disagree with that, Counsel. I think that the IFU is intended as a general guideline. Pelvic surgeons are made aware of risks of pelvic surgery when they're resident doctors when they do their first episiotomy. They know that can result in dyspareunia.
I mean, we all have a fund of knowledge of knowing complications of surgery whether we're using mesh or native tissue.
Q So if a corporate witness for Ethicon and Johnson & Johnson testified that that was the standard that Ethicon and Johnson & Johnson should follow, you would disagree with that?
A Yes, I would.

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A Yeah. I don't know what you mean by that. Physician's experience and clinical experience and knowledge base varies. So is mine different than my mentor's, Dr. Bent or my colleague, Dr. Harry Johnson? It may very well be. It most certainly is. My clinical experience is my clinical experience. It's unique to me.

Q Would you agree with me that you might know about a potential complication from your own experience that another doctor might not know about?

MR. SNELL: Objection.

A I would agree that there are complications I've had that other doctors may not have had and vice-versa. That's certainly true in clinical practice. We all have unique complications, and I think if you practice long enough, you'll probably have every complication in the book at some point in your career.

Q So you'd agree with me, then, that another doctor has an experience that he might not know about; correct?

MR. SNELL: Objection. Misstates.

A I'm not quite sure where you're going

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with this except to say that we've all experienced unique complications that another doctor may not have experienced, and that's why we have M&M conferences and that's why we call colleagues when we have a unique complication and pick each other's brains. I mean, that's what a collegial relationship is about.

Q Right. I think you're maybe misunderstanding my question. I'm not asking you about whether another doctor might have experienced a different complication than you haven't experienced. I'm asking about complications that another doctor might not know about. So I'm going to reask the question again and ask you to focus on that.

MR. SNELL: Hold on. I'm going to object because your questions were about experiencing complications. It wasn't about knowledge.

MR. FAES: No. It's about complication.

MR. SNELL: Complications experience. You asked him two or three times and he testified to that. Now you're changing. I just don't want

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you to break --

MR. FAES: I don't think I am.

BY MR. FAES:

Q Let me ask the question and ask you to focus on the question if you can.

Would you agree with me that you might know about a complication from your own experience that another doctor might not know about?

MR. SNELL: Objection. I think that was asked and answered.

A Okay. So I might have a complication that another doctor might not know about. I mean, that's obvious. To me, I might have a complication with a surgical procedure that I'm doing that another doctor would not have experienced and would not know about.

Q Have you ever studied the question of what information needs to be in an IFU, instructions for use?

A Have I ever studied that? I think I've answered this before. I'll answer it again.

My understanding of an IFU is that it provides a general background and guidance noting potential risks and complications of a medical

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device, if that's what we're talking about, without needing or being required to list every potential complication or risk related to it.

Q Are you relying on any objective standard from any source for that opinion?

A Any objective standard? Have I read that as a specific guideline? No. That is my own general understanding of IFUs that I've understood during my career.

Q Would you agree with me that you're not a biomedical engineer?

MR. SNELL: Objection.

A I would disagree with that, Counsel. I think I don't have a degree as a bioengineer, I don't have a Ph.D or a doctorate, but I have a lot of experience in reference to the use of polypropylene mesh and pelvic reconstructive surgery, and, as such, I have been privy to how polypropylene mesh reacts in the human body. I've been a participant at various summits and industry meetings where we've looked at and evaluated properties of polypropylene mesh.

Q So you hold yourself out to the public as a biomedical engineer; is that accurate?

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Q Would you agree with me that Ethicon did not design the mesh arms of the Prolift to deform?
A Deform in what way? Mesh arms are able to conform and to be pliable. So can they deform as pliability and deformable? I'm not sure. When you place the Prolift and you place the arms through the cannula, once the cannulas are removed, the mesh arms remain in place.
So do they deform once they're in place? Are they incorporated into the tissue?
Q My question is do you agree that Ethicon didn't design the mesh to deform?
MR. SNELL: Objection. Asked and answered.
A I think the mesh was designed to be very pliable, and in being pliable, pliability allows the mesh to deform but in a positive way.
Q So you believe that Ethicon did design the mesh to deform but only in a positive way?
MR. SNELL: Object. Misstates.
A I believe that Ethicon designed a polypropylene microporous mesh to be compatible, biocompatible and to provide for native tissue

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in-growth to provide for anatomical repair of the prolapse. And I would need to see what the definition of deformity is before I answer that question definitively.
Q So as you sit here today, do you know whether or not one of the intentions of the Ethicon designers, when designing the Prolift arms, was that the mesh would deform?
A I don't know specifically if that was the word they used in designing the mesh not deforming.
Q Would you agree with me that Ethicon did not design the Prolift mesh to shrink?
A They did not design the mesh to shrink. That's correct.
Q Would you agree with me that excessive contraction or shrinkage of the tissue surrounding the mesh is a potential adverse reaction from the Prolift mesh?
MR. SNELL: Objection. Form.
A No, I would not agree with that, Counsel.
Q So if that's a potential adverse reaction of the Prolift mesh listed in the IFU,

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you would disagree with that?
MR. SNELL: Objection. Foundation. Misstates the evidence.
A I think that any surgery can lead to contraction; okay? So that's a known risk of any surgery we do, is contraction.
Q Would you agree with me that excessive contraction or shrinkage of the tissue surrounding the mesh is a potential adverse event of the Prolift procedure?
MR. SNELL: Objection. Form.
A I don't think it's specific to the Prolift procedure. I don't think it's specific to the polypropylene mesh. I think it's specific to surgery in general that one can have contraction and shrinkage of tissue. I have seen this with native tissue repair. Seen that with posterior, anterior colporrhaphy without the use of mesh or permanent suture.
Q Right. But I'm asking specifically about mesh and excessive shrinkage --
A Right.
Q -- and contraction. Strike that. Excessive contraction or shrinkage of tissue

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surrounding the mesh. Is that a potential adverse reaction of the Prolift mesh?
MR. SNELL: Objection. Asked and answered.
A And I've answered that question. My answer to that is no, I do not believe it's related specifically to the mesh.
Q And so you believe that that's incorrect information?
A I'm saying that that information is relevant to the surgery in general and not specific to the implant.
Q Do you think that that is an appropriate warning for Ethicon to put in their -- in the adverse reaction section of the IFU for their Prolift mesh device?
MR. SNELL: Objection. Vague as to "that."
Q Is it vague as to that? Do you know what I'm talking about? Do I need to restate the question?
MR. SNELL: Objection.
A You can restate the question, Counsel.
Q Do you think that putting the warning

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in the adverse reactions section of the -- let me reask this because now I'm all befuddled here with Burt's objections.

You think a warning in the Prolift IFU that excessive contraction or shrinkage of tissue surrounding the mesh is an appropriate warning to put in the adverse reaction section of the IFU?

MR. SNELL: Objection. Misstates.

A So I think the IFU can list potential complications of the device and of the procedure and contraction. Scarring is a known risk. It's known to anyone doing pelvic surgery that that is a known potential risk of surgery, whether the mesh is there or not.

Q But my question is is it an appropriate warning to put in the IFU that excessive contraction or shrinkage of the tissue surrounding the mesh may occur?

A If they put --

MR. SNELL: Objection. Go ahead.

A If that's in the IFU warning, then Ethicon deemed that an appropriate thing to mention. Yes.

Q So would that warning be an appropriate

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warning to put in the instructions for use for the Prolift device since the device was first marketed, that Ethicon knew that was a risk?

MR. SNELL: Objection.

A So when they -- are we --

Q Let me restate the question.

A Restate it.

Q If Ethicon knew at the time that the Prolift was launched that excessive contraction or shrinkage of the tissue surrounding the mesh was a potential adverse reaction, would it have been appropriate to include that in the adverse reaction section of the IFU at launch?

MR. SNELL: Objection.

A No, I don't think so, because as we've already mentioned, IFU, it does not need to be all inclusive of every potential risk or complication of the proposed surgery and the medical device being employed. And so I think Ethicon has the discretion and knowledge to know which risks are to be listed.

Q Is it an appropriate warning now as we sit here in 2018?

A The contraction --

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MR. SNELL: Objection. Form, vague, overbroad.

A They chose to list that as a potential complication. I'm not here to tell you whether that's right or wrong, but I am telling you that I don't believe that contraction of tissue is a result of mesh implantation.

Q So if I understand you correctly, you believe it was inappropriate at the time of launch but now you can't tell me if it was right or wrong?

MR. SNELL: Objection. Misstating his testimony completely. Argumentative too.

A That's not what I said. I said that I don't believe -- you asked me if I think that should be in the IFU and my answer to you is I don't know if it should be in the IFU or not but that I don't believe it's related to the mesh.

Q Actually, my question wasn't should it be in the IFU now? I asked -- well, maybe I did or I didn't.

MR. SNELL: Yes.

Q So I'll let the record speak for themselves.

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My question now is do you believe, today, that it's appropriate to put a warning in the Prolift mesh IFU that excessive contraction or shrinkage of the tissue surrounding the mesh is a potential adverse reaction?

MR. SNELL: Objection. Asked and answered, I believe.

A I will again state for the record that I cannot tell you whether that is an appropriate warning to have in the IFU, then or now, because I don't believe -- it is my opinion, based on my clinical experience, that I don't believe that's a result of the medical device itself but, rather, surgery. So that's my statement.

Q So if Ethicon were to list that as a potential adverse reaction of the medical device itself, you believe that would be incorrect information?

MR. SNELL: Objection.

Q Is that accurate?

MR. SNELL: Objection. Foundation. Improper hypothetical.

A I would say that that is Ethicon's prerogative to list whatever potential

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statement?
A Well, I think that that is left intentionally vague and to the discretion of the pelvic surgeon. So if you're asking me what I consider high risk surgical patients, I can answer that question.
Q Okay. What do you consider high risk surgical patients?
A Okay. So if we're talking about anterior vaginal wall prolapse, cystocele, loss of apical support, I would consider a high risk surgical patient, an individual who I might not want to operate on abdominally.
I take a lot of factors into consideration when I choose a surgical approach. I have patient's age, her medical history, her past surgical history.
THE REPORTER: Patient's age what?
A Stage, medical history, surgical history, the stage and location of pelvic organ prolapse, whether she's had previous surgeries. And all of this plays into my ultimate decision as to whether she represents a high risk surgical patient.

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Q So using your definition of high risk individuals, do you believe that pelvic organ prolapse vaginal mesh repair should be limited to high risk individuals?
MR. SNELL: Objection to form.
A I think it should be limited to those patients that you deem appropriate candidates and I would need to know more specifically regarding what is considered a high risk surgical candidate. A high risk surgical candidate is not someone I want to operate on.
Q Do you agree that current evidence on the safety of transvaginal mesh repair of anterior and posterior vaginal wall prolapse shows that there are serious but well-recognized safety concerns?
MR. SNELL: Objection.
A I believe that we're all aware of potential risks of utilizing transvaginal mesh.
Q So you'd agree with that statement?
A There are risks of traditional surgical repairs as well.
Q You would agree that transvaginal mesh repair of anterior or posterior vaginal wall

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prolapse should only be used in the context of research?
A I think that ideally it is used in research settings, but I would also take point as an expert that not all surgeries utilizing transvaginal mesh need to be part of a research trial or cohort.
Q So you would disagree with that statement?
A I would disagree with that statement.
Q Have you read the NIHCE, the National Institute for Health and Care Excellence guidelines that were issued in December of 2017?
A I have read them.
Q And did you rely on them for issuing your opinions in this case?
A I may have. Yes.
Q Would you agree that if a procedure is only used in the context of research, it's essentially experimental; right?
MR. SNELL: Objection.
A No, I do not agree with that.
Q So you don't think that if a procedure is only being used in research studies, it's

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experimental?
MR. SNELL: Objection. Asked and answered.
A No, I don't. I don't agree with that.
Q Do you agree that synthetic mesh for pelvic organ prolapse should only be used in complex cases with recurrent prolapse in the same compartment?
MR. SNELL: Objection. Form and foundation.
A I know that statement and I don't agree with that statement.
Q So you disagree -- so you know that it comes from the European Association of Urology's treatment guidelines; right?
A I believe that's where it's coming from. I know what our European colleagues have said. Yes.
Q So you disagree with the European Association of Urology in that regard?
MR. SNELL: Objection. Asked and answered.
A Yes.
Q Would you agree that the currently

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available literature does not support the routine use of transvaginal mesh for prolapse repair?
MR. SNELL: Object.
Q Let me actually ask a different question. Would you agree with me that currently available literature does not support the routine use of transvaginal mesh for prolapse repair but that that does not apply to the use of transabdominal mesh used during a minimally invasive or open sacrocolpopexy?
MR. SNELL: Objection. Form and foundation.
A So you need to -- please just state that question again.
Q Well, let me back up. Have you read the Canadian Urological Association's treatment guidelines for pelvic organ prolapse repair issued in 2017?
A '17. Yes, I did read that.
Q Are you aware that that guidance states that the currently available literature does not support routine use of transvaginal mesh for prolapse repair. This recommendation does not apply to the use of transabdominal mesh used

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during a minimally invasive or open sacrocolpopexy?
A I'm familiar with that statement.
Q Do you disagree with that statement?
MR. SNELL: Object.
A I disagree with that statement. Yes.
Q Do you agree that a reasonable argument can be made that as a result of very serious complications that can occur from the Prolift, the risks outweigh the benefit and there's -- well, strike that.
Would you agree with me that when you take into account the most serious complications Ethicon knows have happened to women with the prolapse, when you look back, a reasonable argument can be made that as a result of those very serious complications, the risks outweigh the benefit and it shouldn't have been sold?
MR. SNELL: Objection.
A No, I don't agree with that statement, Counsel.
Q So if the chief medical officer of Ethicon and Johnson & Johnson agreed with that statement, you would disagree with them; is that

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accurate?
MR. SNELL: Misstates, foundation. Go ahead.
A Are you telling me that the chief medical officer stated that Prolift should never have been sold?
Q I'm telling you that the chief medical officer agreed that when you take into account the most serious complications that Ethicon knows have happened with the Prolift, when you look back, a reasonable argument can be made that as a result of those very serious complications, the risks outweighed the benefit and it shouldn't have been sold?
MR. SNELL: Objection. Foundation. Misstates the evidence. Asked and answered as well. He's already told you his view on that.
A Yeah. My view on that is that my clinical experience and my review of the literature support the use of Prolift.
Q And you've never seen the testimony of the chief medical officer of Ethicon and Johnson & Johnson, Jim Hart?
A No, I have not.

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Q And that's not something that you considered in reaching your opinions in this case?
A No. I considered my opinions based on review of the literature specifically with attention to Level 1 and Level 2, not to expert testimony and less quality evidence. So I did focus my expert report on review of the literature, Level 1, Level 2 evidence and statements and email communication from industry.
Q So you don't think that the testimony of Ethicon's chief medical officer can offer any relevant opinion regarding the safety and efficacy of the Prolift device?
A I can't comment on that because I didn't read his statement.
Q Is that something that you would have liked to have reviewed prior to issuing your opinions in this case?
A I'm not sure it would have had any bearing on my opinion, on my report.
Q But would you have liked to have seen it?
MR. SNELL: Objection. Asked and answered.

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A Okay. So we're talking about erosion. There's lots of things that lead to erosion, Counsel, and contraction and scarring is due, in my opinion, to surgery.

You don't have contraction and scarring if you don't use a scalpel. If you use a scalpel, you're going to have some contraction and scarring. Tissue never regains its initial strength. And I don't believe that contraction and scarring is a result of the mesh.

Q Never? It's never? So you believe that it's never a result of the mesh?

MR. SNELL: Objection. Asked and answered about seven times. He's already testified to that numerous times, Counsel.

A Again, I don't believe it's related to the mesh. That is my statement, my testimony.

Q So then you believe that a mesh which causes excessive shrinkage and contraction can't be a defect in the device because it doesn't occur; right?

MR. FAES: Object.

A Right. I don't think -- again, answering that question again, I do not believe

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that excessive contraction and shrinking, whatever you just said, if you want to restate it. But I think I've tried to make my point. I do not believe that histological changes are a result of a defect in the mesh.

Q On page 12 of your report, you state that "Assuming that pain or dyspareunia are due to the Prolift or the Gynemesh PS is speculative and non-evidence based."

Do you see that, page 12, last sentence of the continuing paragraph.

MR. SNELL: Okay. Sorry.

Q Do you see that, Doctor?

A Yes, I do.

Q So is it your opinion that pain and dyspareunia can never be due to the Prolift or Gynemesh PS?

A My opinion is that there are many causes for pain and dyspareunia and sexual dysfunction, and that if we look at studies that look at those complaints in the general population presented to either primary care physician offices or presenting in our study, that we looked at evidence at the prevalence of dyspareunia and

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pelvic pain in patients presenting to our clinic at Hopkins with pelvic organ prolapse, we see that there's a very high incidence of those conditions at baseline. And so I do not believe that mesh implantation, whether it's Prolift or Elevate, contributes necessarily to dyspareunia.

Q So let me see if I can answer it, ask it as a yes-or-no question, because I'm running out of time. I'll try to keep it very simple.

Doctor, do you believe that pain can potentially result from a Prolift mesh?

MR. SNELL: Objection. Asked and answered.

A I believe that pain, just like erosion, can be multifactorial and that there can be -- by that, I mean there can be many things that lead to pain and painful intercourse, dyspareunia that are not necessarily related to the use of transvaginal mesh.

Q That's not what I'm asking. I'm asking the question very specific and I'm using your language from your report.

Do you believe -- and I'm asking you a yes-or-no question. Do you believe, yes or no,

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that pain can be due to a Prolift mesh? I'm not asking about multifactorial or anything else. I'm asking if pain can be due to a Prolift mesh?

MR. SNELL: Objection. Asked and answered.

A So my statement here is that it's speculative and nonevidence-based. And so as far as you can say a yes-or-no answer to that, I don't think you can. I think that you need to take cases on a case-by-case basis and understand that there are lots of things that can contribute to pelvic pain and dyspareunia and that we can't just say oh, well, you had a mesh placed and, therefore, your pain is related to the mesh.

Q So I just want this to be clear. You're stating that you can't answer yes or no to the question of whether or not pain can be due to Prolift?

MR. SNELL: Objection. Form. Misstates.

A Right. I can't answer that definitively. No.

Q Would you agree with me that you can't state yes or no that dyspareunia can be due to

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Prolift?
A For the same reasons I've just enumerated, I can't say that dyspareunia would be directly related to Prolift.
Q Doctor, on page 3 of your report, you discuss the erosion rates for the TVT and TVT-O product.
A Yes.
Q Would you agree with me that there's nowhere in your report where you discuss what the overall rates of mesh exposure are for the Prolift or Gynemesh PS product?
A That could be.
MR. FAES: How are we doing on time?
THE REPORTER: You are right at the end.
MR. FAES: I'll reserve my one minute for what I'm sure will be Burt Snell's hour-and-half direct. And can we take a quick break?
MR. SNELL: If you want to.
(Break taken, 4:16 - 4:21 p.m.)
EXAMINATION BY MR. SNELL:
Q All right. Burt Snell, attorney for

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Ethicon and Johnson & Johnson.
Dr. Ellerkmann, I just have some followup questions on some of the topics that you've been discussing with Plaintiff's counsel today, the first of which -- well, I'll come back to that.
Let's kind of start in the beginning with some of the topics. You recall being asked about your opinions as to the adequacy of the Prolift IFU?
A Yes.
Q And I believe you testified to Plaintiff's counsel you believe that it was adequate?
A Yes.
Q Do you have expertise as to the expected knowledge of the pelvic surgeon who might perform the Prolift?
A Yes, I do, because I am one.
Q Do you have expertise and knowledge with regard to the expected knowledge of pelvic surgeons coming out of residency?
A Yes, I do.
Q How is that?

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A Well, I have been an associate residency director at Johns Hopkins, as my CV attests to. I've taught residents for all of my career post-residency myself. I've been involved with fellowship training. And so I am very aware of what they require by the RFC, Residency Review Committee, in terms of what their fund of knowledge needs to be, what their surgical experience needs to be at the time of graduation from residency.
Q And did you apply that as a standard for your IFU opinions?
A Yes, I did.
Q Have you talked Prolift to any surgeons?
A Yes, I have.
Q Can you tell us the types of surgeons?
A I've taught Prolift surgeries to residents more than I can count, fellows of which I've had over 20 in my career, many of which you know. I've taught Prolift to some generalists in the community here as well as to other urogynecologists.
Q Did you utilize that as a standard and

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basis for your IFU opinions with regard to the adequacy of the Prolift IFU?
MR. FAES: Objection.
A Yes, I did.
Q Are you familiar with the board certification process -- strike that.
Are you familiar with the knowledge base tested and evaluated with the OB-GYN board certification process?
MR. FAES: Objection.
A Yes, I am.
Q Same question with regard to female public medicine and that subspecialty board. Are you familiar with the knowledge base, the expected knowledge base of surgeons sitting for that board?
MR. FAES: Objection.
A Yes, I am.
Q For those board certifications, is there an expected required knowledge with regard to complications that can come from pelvic organ prolapse surgery?
MR. FAES: Objection.
A Yes, there are.
Q With and without mesh?

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or presented at. One, let's take number 4, Pelvic Organ Prolapse and Biomaterial Augmentation.
A Correct.
Q Is that a course?
A Where was that?
Q Sure. Number 4, Pelvic Organ Prolapse and Biomaterial Augmentation.
My question to you -- are you there?
A Oh, yes. Yes, I remember that very well. I went and spoke to the European Association of Gynaecologists. That was in Bern, Switzerland, and we spoke. That was at that time with Cook and we were speaking primarily about Surgisis. That was a xenograft that Cook was developing for pelvic floor reconstruction.
Q In 2000, were you analyzing biomaterials and specifically how they performed in the pelvic organ prolapse application?
MR. FAES: Objection.
A Yes, I was. In fact, Counsel, as a fellow, I was very involved in developing and working with my co-fellows and subsequently as a junior attending. We did several pilot studies looking at some of the earliest biological grafts,

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xenografts, including Tutoplast and Surgisis, and seeing whether there were improved outcomes in anatomical repair and subjective outcomes with their use for transvaginal augmentation.
Q Another one, if you just go to number 22, Biomaterials in Gynecologic Surgery: A Review of the Literature and Current Applications. You were the invited speaker at the American Urogynecology Association Annual Scientific Meeting in 2005. Do you see that reference in number 22?
A Yes, I do.
Q And in connection with that, would you have analyzed biomaterials?
A Yes.
Q Would you have presented to pelvic surgeons on biomaterials and their use in these applications?
A I did. That was a presentation.
Q Would that presentation have included the pelvic organ prolapse application?
A Absolutely. Yes.
Q Would that presentation have included the use of a macroporous polypropylene mesh for

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treating pelvic organ prolapse?
A Yes, it would have.
Q Would that presentation have included your analysis and knowledge as to the design and the utility, if any, of such a device?
MR. FAES: Objection.
A Yes.
Q You told Plaintiff's counsel you also have experience analyzing the design of devices in cadaver labs?
A Yes.
Q Number 25, for example, lists a cadaver lab you did on Prolift and other devices. Do you see that?
A I do. It was here in Baltimore.
Q Did you do other cadaver labs on Ethicon devices where you analyzed the design of the device and the safety in places other than Baltimore?
MR. FAES: Objection.
A Yes, I did.
Q You were asked about the materials list that my firm put together and I believe you testified you did not read the two company witness

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depositions that we put on that. Is that correct or wrong?
A That's correct.
Q Okay. Did you review, though, the company documents that we sent to you?
MR. FAES: Objection.
A I reviewed as much as I could, yes, of those documents.
Q Had you been reviewing company documents and materials pertinent to the Prolift actually even before becoming an expert in this litigation?
MR. FAES: Objection.
A I reviewed documents in the past from Ethicon as a preceptor and at our summit meetings. Yes.
Q And did you bring today response to plaintiff's deposition notice that was marked as Exhibit No. 1 the materials that you've considered and relied upon?
A I did. Yes.
Q Can you describe that for the court reporter, please, what you brought.
A So I have brought copies, both hard

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copy and a flash drive containing all the literature that I had been able to review in preparation for my expert report and for this deposition.

Q Does that also include company documents such as the IFU and professional educations lines?

A Yes, it does.

Q Does that include documents from Ethicon pertaining to the design of the Prolift?

A Yes, it does.

Q You were asked about if you did an analysis. Did you do an analysis of the medical literature with regard to Prolift to formulate your opinions?

A Yes, I did.

Q Can you tell us in general how you went about doing that analysis?

A So that analysis has been ongoing since I was introduced to transvaginal repairs. And so in addition to the literature reviewed for today's deposition and for the report, the foundation for my opinion and expert report is based on my experience, my clinical experience, my

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communications with other colleagues, and my review of the literature over the years as well as specific review of the literature for preparations for the report.

Q And there's been questions about Gynemesh PS and Prolift. Does Prolift use Gynemesh PS?

A Yes.

Q Do you view outcomes and studies on those two devices as being relevant and similar?

A I do. Yes.

Q Is that the way you considered those devices back when you were using and teaching them before becoming an expert?

A Correct. So we know that Gynemesh PS is the same mesh that's used in Prolift. The difference is in the design, in the cut of the mesh.

Q And would Gynemesh PS and your personal use of it, did you need to cut that mesh and trim it before using it as well?

A I have on occasion, yes. It came in sheets, so we cut it all the time when we used it for abdominal sacrocolpopexy.

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Q You were asked about whether you separated Prolift studies into different buckets or categories. Do you recall in general those types of questions?

A I do.

Q Did you review the overall data an Prolift to evaluate and help form your opinions?

MR. FAES: Objection.

A Yes, I did.

Q Even as you sit here, do you recall any specific studies that actually stated that Prolift was defective?

MR. FAES: Objection.

A I didn't see any study that specifically stated that Prolift was defective.

Q In formulating your opinions that Prolift was not defective, have you described your methodology earlier?

MR. FAES: Objection.

A I believe I did describe my methodology.

Q You were asked about pathology. Have you seen any medical literature that concerns pathology of explanted mesh?

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A Yes, I have seen literature that looks at histology of explanted mesh.

Q Is that something you would have seen not just in connection with your role here, but is that something that will be part of your regular reading of the literature?

MR. FAES: Objection.

A Absolutely. I mean, as I noted to Counsel earlier, even years ago with my fellow, we've looked personally at explanted mesh microscopically in trying to obtain a better idea of what was going on histologically with that material.

Q And when you were doing these presentations to other pelvic surgeons, whether at the annual AUGS scientific meetings or otherwise, as part of that and devising your opinions at that time with regard to the biocompatibility of mesh for the prolapse application, did you consider clinical studies published on the mesh?

MR. FAES: Objection.

A We considered -- I considered clinical studies and I also looked at the review of the biological grafts as well as synthetic grafts that

Q And is that part of your professional experience that you rely upon for your opinions?
A It is. I personally view every pathology report on my patient.
MR. FAES: We're going to have to take another break if you keep going much longer.
Q I'm just checking.
And in your expert report, did you discuss your opinions on the design of the Prolift device?
A Yes, I did.
Q Did you discuss the potential benefits -- strike that.
Did you discuss the benefits as you saw them with regard to the components and parts to the Prolift device including Gynemesh PS?
A Yes, I did, previously elaborated on that briefly here today.
MR. SNELL: I think that's all. Thank you.
MR. FAES: Thank you, Doctor.
(Deposition concluded at 5:28 p.m.)

STATE OF MARYLAND)
COUNTY OF HARFORD)

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I further certify that the proceeding was recorded stenographically by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor an employee of counsel, nor related to any of the parties, nor in any way interested in the outcome of this action.

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